contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.

(f) Form FD–2892 is the approved form for providing the device listing information required by the act. This required information includes the following:

(1) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list of devices previously submitted on form FDA–2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505 or 515 of the act.

(4) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.

(5) Whether the device, as labeled, is intended for distribution to and use by the general public.

(6) Other general information requested on form FDA–2892, i.e.,

(i) If the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device,

(ii) The reason for submission,

(iii) The date on which the reason for submission occurred,

(iv) The date that the form FDA–2892 was completed,

(v) The owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate FDA classification name for the device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37998, Aug. 25, 1978; 58 FR 46523, Sept. 1, 1993; 64 FR 404, Jan. 5, 1999; 66 FR 59160, Nov. 27, 2001; 69 FR 11312, Mar. 10, 2004]

### § 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FDA–2891(a) at the time of annual registration, or by letter if the changes occur at other times. This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

[69 FR 11312, Mar. 10, 2004]

### § 807.30 Updating device listing information.

(a) Form FDA–2892 shall be used to update device listing information. The preprinted original document number of each form FDA–2892 on which the device was initially listed shall appear on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows: